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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,001	09/22/2000	Yasutaka Ishii	3273-0121P	5966
2292	7590	06/07/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			SOLOLA, TAOFIQ A	
PO BOX 747			ART UNIT	
FALLS CHURCH, VA 22040-0747			PAPER NUMBER	

1626

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/622,001	<b>Applicant(s)</b> ISHII ET AL.	
	<b>Examiner</b> Taofiq A. Solola	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-3 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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Claims 1-3, 14-21, are pending in this application.

Claims 4-13, 22, are canceled.

***Response to Restriction Requirement***

The election of the process of making  $\alpha$ -hydroxy- $\gamma,\gamma$ -dimethyl- $\gamma$ -butyrolactone comprising the reaction of 2-propanol with ethyl acrylate in the presence of N-hydroxyphthalimide, in the Paper filed 4/15/04, is hereby acknowledged. There is no indication the election is made with or without traversal. Therefore, it is deemed made without traversal, and the restriction is made FINAL. The claims are drawn to different processes of making different compounds. The elected process corresponds to claims 1 and 21. Therefore, claims 2-3, 14-20, are withdrawn as being drawn to non-elected subject matter.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 21 are rejected under 35 U.S.C. 101 because 101 because the claimed invention is not supported by either an asserted utility or a well established utility. Under US patent practice the process of making a compound is not a utility, the compound must have an asserted or a well established utility. In the instant process, claims 1 and 21 fail to set forth/recite the compound being made. By amending claim 1 to recite  $\alpha$ -hydroxy- $\gamma,\gamma$ -dimethyl- $\gamma$ -butyrolactone as the product the rejection would be overcome.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 21 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above.

Claims 1, 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to provide written description for how to perform the instant process using any compound capable of forming stable radical of (A1), (A2) and (A3) or any radical scavenging compound of (B1), (B2) and (B3). This is also true of metallic compound in claim 21. Applicant must show possession of the invention by describing it with all the claimed limitations. *Lookwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997). By reciting the process as comprising the reaction of 2-propanol with ethyl acrylate in the presence of N-hydroxyphthalimide in claim 1, and reciting the specific metallic compound(s) in claim 21, the rejection would be overcome.

Claims 1, 21, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making  $\alpha$ -hydroxy- $\gamma,\gamma$ -dimethyl- $\gamma$ -butyrolactone comprising the reaction of 2-propanol with ethyl acrylate in the presence of N-hydroxyphthalimide, does not reasonably provide enablement for making all organic compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claimed process is not believable on its face.

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For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

- 1) Breadth of claims.
- 2) Nature of invention.
- 3) State of prior art.
- 4) Level of ordinary skill in the art.
- 5) Level predictability in the art.
- 6) Amount of direction and guidance provided by the inventor.
- 7) Existence of working examples.
- 8) Quantity of experimentation needed to make or use the invention based on the

content of the disclosure.

The breadth of the claimed invention involves process of making any organic compound. The nature of the invention is in the field of a process of making chemical compounds wherein applicant is claiming a method of making any organic compound. The state of the prior art is what prior art knows about the nature of the invention. There is no known prior art claiming a process for making all organic compounds. The level of ordinary skill in the art is high but only in process of process of making  $\alpha$ -hydroxy- $\gamma,\gamma$ -dimethyl- $\gamma$ -butyrolactone. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by applicant. In the instant invention the predictability is very low and consequently, the need for higher levels of direction and guidance by applicant. However, the amount of direction and guidance provided by applicant is limited to assays involving process of making  $\alpha$ -hydroxy- $\gamma,\gamma$ -dimethyl- $\gamma$ -butyrolactone comprising the reaction of 2-propanol with ethyl acrylate in the presence of N-hydroxyphthalimide. There are very large

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varieties of processes of making different organic compounds where in different mechanisms are involved. There is no evidence in the specification that established correlation between applicant experiment and a process of making any organic compound. See Ex parte Mass, 9 USPQ2d 1746, 1987. Therefore, the quantity of experimentation required to use the process as claimed, based on applicant's limited disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of experiments. By reciting the process as comprising the reaction of 2-propanol with ethyl acrylate in the presence of N-hydroxyphthalimide in claim 1, and reciting the specific metallic compound(s) in claim 21, the rejection would be overcome.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 21, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 fails to recite the specific reagents and product thereof. Applicant cannot claim all compounds of (A1), (A2) and (A3), capable of forming a stable radical; all radical scavenging compounds of (B1), (B2) and (B3) or all metallic compounds. Also, the product of the reaction is not recited in the claims. Applicant must claim only the reagent compound(s) that embody applicant's invention. Therefore, claims 1, 21, are indefinite. A claim must stand alone to define the inventions, and incorporation into the claims by reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993). In patent examination, it is essential for claims to be precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

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By reciting the process as comprising the reaction of 2-propanol with ethyl acrylate in the presence of N-hydroxyphthalimide in claim 1, and reciting the specific metallic compound(s) in claim 21, the rejection would be overcome.

### ***Specification***

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms and phraseologies, which are idiomatic and not clear. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. For example, see page 3, line 17; page 9, second paragraph, lines 11-13; page 10, first and second paragraphs. See also page 27, lines 1-3 and top of page 35.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, J.D. whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

  
**TAOFIQ SOLOLA**  
**PRIMARY EXAMINER**  
Group 1626

June 1, 2004